DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. 99P–5589]

Medical Devices; Reclassification and Codification of the Absorbable Polydioxanone Surgical Suture

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has issued an order in the form of a letter to Ethicon, Inc., reclassifying the absorbable polydioxanone surgical (PDS) suture intended for use in soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery, from class III (premarket approval) to class II (special controls). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document entitled ''Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA,'' which is immediately in effect as the special control for the PDS suture, but remains subject to public comment and possible future revision under the agency's good guidance practices. The agency is reclassifying this device into class II because new information supplied by the petitioner indicates that special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls. Accordingly, the order is being codified in the Code of Federal Regulations. Any firm submitting

a premarket notification (510(k)) for a new PDS suture will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

DATES: This rule is effective [*insert date 30 days after date of publication in the* **Federal Register**]. The reclassification was effective September 4, 2001.

FOR FURTHER INFORMATION CONTACT: Anthony D. Watson, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

The 1976 amendments broadened the definition of ‘‘device’’ in section 201(h) of the act (21 U.S.C. 321(h)) to include certain articles that were once regulated as drugs. Under the 1976 amendments, Congress classified into class

III all transitional devices, i.e., those devices previously regulated as new drugs, including the absorbable PDS suture. Section 520(l)(2) of the act (21 U.S.C. 360j(l)(2)) provides that the manufacturer or importer of a device classified in class III under the transitional provisions may file a petition for reclassification of the device into class I or class II. Procedures for filing and review of classification petitions are set forth in § 860.136 (21 CFR 860.136).

II. Regulatory History of the Device

Under section 520(l)(2) of the act and § 860.136, on August 25, 1999, FDA filed a petition submitted by Ethicon, Inc., requesting reclassification of the absorbable PDS suture from class III to class II. Class II devices are those devices for which the general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and any other appropriate actions the agency deems necessary (section 513(a)(1)(B) of the act). FDA consulted with members of the General and Plastic Surgery Devices Panel (the Panel members) regarding reclassification of the absorbable PDS suture. The Panel members recommended that FDA reclassify the absorbable PDS suture for soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur, and ophthalmic surgery, from class III to class II. The Panel members also recommended consensus standards and device-specific labeling as the special controls that could reasonably assure the safety and effectiveness of the device.

III. FDA's Conclusion

FDA considered the Panel members' recommendations that the generic type of device, the absorbable PDS suture for soft tissue approximation, be reclassified from class III to class II. After reviewing the data in the petition and after considering the Panel members' recommendations and the comments, FDA, based on the information set forth, issued an order to the petitioner on September 4, 2001, reclassifying the absorbable PDS suture, and substantially equivalent devices of this generic type, from class III to class II. Accordingly, as required under § 860.136(b)(6), FDA is announcing the reclassification of the generic absorbable PDS suture from class III (premarket approval) into class II (special controls). The special control capable of providing reasonable assurance of safety and effectiveness for this device is a guidance document entitled ''Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA,'' which FDA is making available elsewhere in this issue of the **Federal Register**. The guidance document describes a means by which surgical suture devices may comply with the requirement of special controls for class II devices. Any firm submitting a premarket notification (510(k)) for a new PDS suture will need to address the issues covered in the special control guidance. However, the firm needs only to show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness. The special control guidance document reframes the risks identified in the PDS reclassification order to better show how the mitigating measures recommended by the guidance are associated with each risk. The clinical sequelae of the risks identified in the order and of the risks identified in the guidance are identical. FDA notes that the class II special control guidance document incorporates consensus

standards and device-specific labeling. FDA is codifying the reclassification of the device by adding § 878.4840.

For the convenience of the readers, FDA is adding 21 CFR 878.1(e) to inform the readers where they may find guidance documents referenced in 21 CFR part 878.

IV. Electronic Access

Guidance documents are available from the Division of Small Manufacturers, International, and Consumer Assistance (DSMICA) (HFZ–220), Food and Drug Administration, Center for Devices and Radiological Health, 1350 Piccard Dr., Rockville, MD 20850. To receive the guidance document via your fax machine, telephone the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch tone telephone. Press 1 to enter the system and enter the document number (1387) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. The Center for Devices and Radiological Health (CDRH) maintains a home page on the Internet at http://www.fda.gov/cdrh for easy access to information that may be downloaded to a personal computer. Updated on a regular basis, the CDRH Internet site includes device safety alerts; **Federal Register** reprints; information on premarket submissions, including lists of approved applications and manufacturers' addresses; small manufacturers' assistance; information on video conferencing and electronic submissions; Mammography Matters; and other medical device-oriented information. A search capability for all guidance documents may be found at http://www.fda.gov/cdrh/guidance.html.

V. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this reclassification is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of the device from class III to class II relieves all manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act (21 U.S.C. 360e). There was only one manufacturer of this device at the time FDA reclassified it. Subsequently, FDA has found another manufacturer’s device to be substantially equivalent to the reclassified device. The special controls guidance document does not impose

any new burdens on these or future manufacturers. It merely assures that, in the future, devices of this generic type will be at least as safe and effective as the presently marketed devices. These devices are already subject to premarket notification and labeling requirements. The guidance document merely advises manufacturers on appropriate means of complying with these requirements. Furthermore, this rule may permit small potential competitors to enter the marketplace by lowering their costs. The agency, therefore, certifies that this rule will not have a significant economic impact on a substantial number of small entities. In addition, this rule will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) is not required. The information collections addressed in the special control guidance document identified by this rule have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120).

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Section 878.1 is amended by adding a paragraph (e) to read as follows:

§ 878.1 Scope.

* * * * *

(e) Guidance documents referenced in this part are available on the Internet at http://www.fda.gov/cdrh/guidance.html.

3. Section 878.4840 is added to subpart E to read as follows:

§ 878.4840 Absorbable polydioxanone surgical suture.

(a) *Identification*. An absorbable polydioxanone surgical suture is an absorbable, flexible, sterile, monofilament thread prepared from polyester polymer poly (p-dioxanone) and is intended for use in soft tissue approximation, including pediatric cardiovascular tissue where growth is expected to occur, and ophthalmic surgery. It may be coated or uncoated, undyed or dyed, and with or without a standard needle attached.

(b) *Classification*. Class II (special controls). The special control for the device is FDA's ''Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.'' See § 878.1(e) for the availability of this guidance document.

Dated: October 16, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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